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FDA MEETING,

Before Michelle S. Schreadley,
Certified Court Reporter and Notary Public,

At FDA, Atlanta, Georgia,

On April 28, 1999, at 3:20 p.m.

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MR. DYKSTRA: Folks, why don't we get started with the second or maybe the third part of your program. I want to again thank you for your patience with this process and again assure you that we are going to try to capture all of your questions and comments. And if we have answers, we'll capture those too.

We are employing the use of a court reporter, so it will be necessary, if we get to a point where you want to ask a question verbally, if you would stand up and identify yourself for the court reporter, it will help her.

What we're going to do first of all with this session of the program is we have a couple of presenters. Nancy Singer from the Health Industry Manufacturers Association has some remarks that she wants and the Association wants to get into the record. And Betsy Woodward, representing AFDO, Association of Food and Drug Officials, has a short presentation as well.

Once we get through those presentations, then we are going to, we have distributed many of your questions among us here in Atlanta, and we're going to go through them. I can't guarantee that we have answers for all of them, but some of them, we can at least comment on and help the process a little bit more.

And, again, those will be captured in the formal record, and you will see those, as well as hopefully some reasonable answers, on the Internet in the not-too-distant future. So that's what we want to get through this afternoon. Hopefully we can get through it speedily so we can get you all on your way before that traffic starts backing up out there. So let's get on with it. Nancy?

MS. SINGER: Thank you. Good afternoon. My name is Nancy Singer, and I'm special counsel to the Health Industry Manufacturers Association, HIMA. HIMA is a trade association in Washington, D.C., and we have 800 members presently. And we represent 90 percent of the sales of medical devices in all of the United States, and we feel very tied

into the medical-device industry.

I'd like to see how many companies are medical-device manufacturers here? Can I have a show of hands? How many food companies? Can I see how many are in the food industry? Nobody left in foods. How about drugs? Two in drugs. Three in drugs. How about members of consumers? Any consumer representatives or doctors? Okay. So there's mostly industry people in the audience, and the rest of you back there in FDA. So this side of the room is industry, and that side of the room is FDA. It's good to see a little bit about the break-up.

Well, over at HIMA, and me representing HIMA, really appreciate the opportunity to be here today. And we broke up for the telephone conferences, the different centers or the different sites around the country, and this is the ORA site. So I thought my remarks would focus on what action do you propose to enable FDA's Office of Regulatory Affairs to focus on those areas of the greatest risk to the public health. That's what I'm going to be talking about today.

Now, we at HIMA, we believe that FDA has done a terrific job working with medical-device manufacturers in that they've implemented many changes that really have focused the Agency's resources to make the inspection process fairer and more equitable and more efficient. We believe these cooperative efforts really must continue because this will enable patients to have access to safe and effective medical-device technology.

Now, let's look at various roles of different agencies in the industry. Really, medical-device manufacturers see ourselves as the innovators in the diagnosis, care, and treatment of disease, and our success really depends on allowing patients access to safe and effective medical devices. So that's industry.

Now, let's consider where FDA is coming from. FDA officials also see themselves as the guardians of the public health. Their mandate is to foster the introduction of new technology but at the same time to ensure that devices that are designed to treat patients really do not cause any harm to those patients

inadvertently.

One of the ways that the inspector FDA does its job is by inspecting our company's medical-device manufacturers. And during the past few years FDA has really viewed industry as a partner rather than an adversary, and we're just delighted by all the wonderful changes that have gone on.

This really has not always been the case. I remember when I first came to HIMA in 1990, and at the time I was coming to HIMA, Commissioner Kessler, in November of 1990, became the Commissioner of the Food and Drug Administration. And one of the things that he wanted to do, as some of you will recall, is he wanted to take enforcement up a notch. And so he kind of changed the way business was being conducted, and what he did at that time is he said, let's decentralize the power of enforcement. Let's put more power in the individual district offices, and let's keep everybody on their toes.

Let's go into a medical-device manufacturer, find deficiencies, cite them for the deficiency and go into another

medical-device manufacturer and find other deficiencies.

Now, companies looking for consistency and predictability had a big problem with this because we never knew in what area the Agency was going to strike, and there were really no lessons learned because they were going to various companies and finding different things.

At that time, again, in the early '90s, HIMA was upset by this, and we said, the environment is not the way we would like it. We figured we would like to figure out ways to make the system work. What we did is polled our members and said, what can we do to make the inspection process better?

And basically what we came up with is we wanted FDA to conduct preannounced inspections. We also wanted FDA to annotate 483 observations. We wanted them to take these 483 observations and put them in context. For instance, I looked at 50 complaints, and I found out that there was follow-up with relationship to three, a lack of follow-up for three, three out of 50, not just a lack of

follow-up for complaints.

Lastly, the medical-device manufacturers wanted closure. They wanted close-out letters. The Medical Device Industry Initiatives Grassroots Task Force came up with the same suggestions, and FDA did in fact come up with a pilot program where they piloted these initiatives.

What FDA did is they took a survey, surveyed the companies. They surveyed the investigators, and they found out this program was really successful, that it worked. Industry liked it. The investigators liked it. So they began to take the program, and they put it as part of their standard operating procedure. And now the program is being piloted in other centers, and we were just delighted.

Well, that went really well, so we said, let's get more suggestions. We said to the industry, ask your customers. Ask the people you're doing business with. So we had meetings all over the country, and actually we had a meeting right here in Atlanta. During that meeting we asked industry, what are more

suggestions?

We came up with a whole lot of suggestions, and one of the suggestions was, let us in fact conduct joint meetings, joint training. Let's have industry and FDA sit in the same room at the same time and learn about the new requirements. Why should FDA be in the corner all by itself? It doesn't make any sense to us. We should all hear the same thing.

We said, you know, those establishment inspection reports should be given out. Why should a company have to request those and let our competitor know that they are making the request. Give them out automatically. That way we could find out about the conclusions early and often, and we wouldn't have to request it.

Also, we said, let's exclude from warning letters those ideas, those things, that have been fixed. If you go into a company and you take some corrective action, why put it in a warning letter? It's only vindictive, we thought.

Another idea, let's increase the

time to respond to 483's so we can really correct and have a better response, rather than do it very quickly initially. Then if you let us do that and we don't, mention that in the warning letter, if we do get one.

Well, FDA was incredibly responsive, and we were just delighted. In terms of joint training with the southwest region, FDA partnered with industry, and we had joint training on the MDR requirements. We had organized joint training with FDA and industry on the design-control portion of the new quality system regulation. We were just delighted to participate. FDA was in the room. Industry was in the room. The exchange was absolutely terrific.

Additionally, FDA now automatically provides EIR's to companies after they're being inspected. Another program is the new warning letter that was alluded to on the teleconference this afternoon. That program is very effective. The industry was very concerned that FDA would not realize this, because every time industry gets a warning letter, the corporate image goes down. The

stock price goes down. This is very detrimental. And many times, if companies have corrected the items, getting that warning letter didn't really seem so fair to us.

Now, FDA listened to our concerns, and that's the biggest compliment you can pay anyone. They came up with a phenomenal pilot program which will fix the concern. The way this pilot program works is beginning March 29, 1999, after a company has a domestic inspection, FDA will go to that company, and they will have 15 days to respond to a 483 observation.

If FDA is satisfied with the response, and in most instances if a company was a good compliant company, instead of sending out a warning letter, they will send out a postinspectional letter. What the letter will say is basically, you would have gotten a warning letter, but you have corrected or promised to correct those actions. However, if we find at a later date that you have not corrected those actions, done what you promised, we'll take other sorts of regulatory action.

But at least when the company has taken corrective action or promised, they will not be getting warning letters in most instances.

The same sort of program is in effect as a pilot program for labeling violations and for failure to submit a 510(k). There will be an untitled letter. It will not be a warning letter. We are just delighted by this effort. We applaud FDA for working with industry and trying out this new program.

What we learned from the Atlanta site, the question was asked, will these postinspection letters be on the Web, and they said no. It's between FDA and the company. So we're just delighted by that development.

Another initiative which we were very delighted by is that after years industry said, there's a lack of consistency among the various districts. One district is doing one thing. Another district is doing another thing. One district is doing another thing.

They came back to HIMA, you're making these allegations. Give us data. And the industry would say, we can't give you data.

It's anecdotal, and our companies don't want to step forward. FDA said, what do you want to do if you don't give us data?

FDA and industry worked as partners with University of California at Irvine to design a device evaluation inspectional survey. And the way this works is, at the end of an inspection, the investigator will fill out the top portion of the survey, talking about the company's name, the investigator's name, whether a 483 was issued.

Then the company will have an opportunity to fill out how the inspection process worked. The survey will then be sent to the University of California at Irvine, and although the names of the company and the investigator will be on the survey, when they enter the data into the database, nobody will have access to that data.

At the end of six months and at the end of a year, the University of California at Irvine will give us reports talking about what's going on in each of the individual districts. Again, here we will have hard data about what's going on, and industry is just so

pleased that FDA is interested in this data and that they're supporting the program and working with us.

The last program that I'd like to talk about is QSIT, Quality System Inspection Technique. Years ago industry complained about individual deviations rather than looking at what was good in the subsystems. So FDA and industry worked together, and now there are seven subsystems that have been identified.

During an inspection FDA will look at the first four subsystems. If they're working and in place, then FDA will be satisfied. We're very delighted by this program. They piloted it in three districts. The results from the pilot program found that in these investigations companies were very pleased and the investigators were very pleased. So this is another initiative that is going to start the first quarter of the year 2000, so we're just delighted.

So in conclusion, FDA and industry working together have made tremendous progress, in working together, making this inspection process better for all the parties involved.

We believe that this interaction should serve as a model across the Agency, across all programs, to make sure the consumers have safe and effective products. We're delighted with all the good work going on, and we urge FDA to continue. Thank you very much.

MS. WOODWARD: Good afternoon. I'm Betsy Woodward, Executive Director of the Association of the Food and Drug Officials, which is a 103-year-old organization of federal, state and local regulatory officials and associated industry, comprising now about 700 members. I'm pleased to offer today some of the comments to Docket No. 99N-0386, on behalf of Joe Corby, on behalf of AFDO.

I'll make some formal comments, and I'll have comments specifically relating to ORA and the State's working relationship with ORA.

AFDO is proud of its tradition in working with federal agencies whose mission parallels ours for developing strategies to resolve and promote public health and consumer protection issues related to the regulation of foods, drugs and medical devices and consumer products. AFDO applauds the openness of FDA

and its willingness to seek stakeholder input.

FDA requested that stakeholders address five questions, and we provided the following comments to those five questions. The first question was: What actions do you propose the Agency take to expand FDA's capability to incorporate state-of-the-art science into its risk-based decision making?

Our response is that AFDO strongly supports decision making based on sound science and improved risk-assessment tools. The FDA can expand its capability by support and utilization of available university and regulatory networks through cooperative activities, not the least of which is the Joint Institute of Safety and Nutrition, JIFSAN, with the University of Maryland.

Through appropriate utilization of JIFSAN, FDA should delineate and prioritize public-health issues requiring science basis, particularly those where current science is weak, emerging or in many, many cases nonexistent.

JIFSAN in turn should incorporate stakeholders in its own internal setting of

priorities. AFDO believes that JIFSAN offers a unique academic partnership that can enrich FDA's decision-making science needs.

JIFSAN should also be used to evaluate other science that impacts on the Agency's mission and in doing so should utilize an advisory group which offers a cross-section of FDA's networks with state and local governments, consumer groups and other academic entities.

Most decision making is set in a scientific, social, political and regulatory framework, which makes it more important for all of these to be brought to the decision-making table to ensure the necessary buy-in and support of any decision. We cannot operate in a vacuum in any of these areas.

We also believe there is a need for FDA to counsel with other regulatory officials from federal, state and local governments regarding their experiences in addressing various food-safety issues.

State officials should continue to be utilized by the FDA, using the credentialing process, to provide valuable input into

proposed regulations and regulatory-enforcement schemes the agency may utilize to obtain compliance.

Additionally, AFDO believes that academia must be continually utilized on advisory committees and work groups which are designed for dealing with particular public-health concerns.

It is very important that our scientific messages and decisions be very clear, and we ask the question, do they result in the action warranted? Science and public health is currently rapidly evolving, and it is extremely important that we in the regulatory community be uniform in our message. This requires very, very good communication, which we have seen improving over the past five years, as Nancy Singer so effectively pointed out.

The second question was: What actions do you propose to facilitate the exchange and integration of scientific information to better enable FDA to meet its public-health responsibilities throughout a product's life cycle?

AFDO has previously testified at public meetings that FDA must be the scientific leader and singular body for dispersing scientific information to government at all levels. AFDO's vision of a national food-safety system recognizes the critical nature of this matter as we continue to promote this concept.

Although state and local governments should continue to provide input on products throughout its development and marketing life cycle, FDA needs to be the centralized body for publicizing the final decision on scientific matters.

FDA cannot assume this leadership role without the buy-in of the stakeholders. Therefore, it necessitates that FDA develop a forum, perhaps an advisory committee, to openly discuss the issues which arise. The Agency is tending to do this through the use of public meetings, but frequently the notice is short and many who should be involved cannot.

FDA needs to look at a wide variety of and a more long-range approach to anticipate issues where public health and science must

converge to bring resolution in a decision-making situation.

To implement an effective integrated approach to exchange of scientific information of regulatory significance, CFSAN and/or FDA needs to develop a streamlined internal tracking system that will ensure state officials receive timely responses to inquiries.

FDA technical staff should be empowered to provide answers without forwarding draft responses through multiple layers of bureaucracy. State officials should be willing to accept a verbal reply, if possible, although FDA must be sensitive to the needs of state officials who may need responses in writing to convince regulated industry or consumers of the regulatory position on an issue.

State officials can no longer wait months to receive replies on scientific or technical matters. This is particularly important when dealing with regulatory issues where it involves an interpretation of federal law or regulation because most state laws mirror the federal law.

What action do you propose, question No. 3, for educating the public on this concept of balancing risks against benefits in the public health decision making?

Articles on risk, written in laymen's terms and giving examples from everyday life, should be used in any FDA documents that are produced for the general public. Certainly analogies have been used by the most effective teachers in our lifetime, and they need to be used in these documents. Only by giving such examples can the general public understand risk as it refers to the safety of food and drugs.

FDA public affairs specialists should be encouraged to continue to address health risks and the importance of consumer education with all interested persons and with groups with whom they meet.

Furthermore, AFDO supports the formation of state task forces comprised of all public-health stakeholders within that state for the purpose of debate, education and communication.

Because the Agency must allocate,

this is question four, its limited resources to achieve the greatest impact, what actions do you propose to enable FDA and its product centers to focus resources on areas of greatest risk to the public health?

Where there are issues that involve a perception that FDA disagrees philosophically with the industry or category of regulated products, FDA must meet both privately and publicly with these stakeholders to ensure on the record that the perception is incorrect.

For example, if the public or some segments of the industry continue to distrust FDA with respect to the regulation of dietary supplements, little headway can be made with respect to ensuring the safety and proper labeling of the products in the marketplace or the development of future products between the Agency and the industry and the consumers.

AFDO also encourages FDA to better establish and maintain its communication network with state and local government agencies, and certainly ORA has been a model agency, model group within the agency, to do this.

On occasion FDA regional and district guidance or response to state and local governments differ from what the FDA centers are saying. This results in a confused message for state officials. AFDO suggests that further development of field-coordinator positions in sensitive high-risk areas, such as product recalls and FDA epidemiological investigations, so those individuals can serve as singular contacts during serious events.

Question No. 5, because the Agency wants to assure that stakeholders are aware of and participate in this modernization, what additional actions do you propose for enhancing communication processes that allow for ongoing feedback and/or evaluation of our modernization efforts?

AFDO supports the continuation and/or the development of work groups to provide necessary feedback and evaluation of serious health matters. Nancy Singer just presented several to us. AFDO hopes FDA can continue to fund the activities of such groups as the National Integrated Food Safety System Work Groups, the FDA/AFDO Recall Work Group,

the Foodborne Outbreak Response Coordination Group, the FoodNet and others established to coordinate and better utilize government resources at all levels.

The Office of Regulatory Affairs, which our meeting specifically focuses on today, holds a special relationship with state officials. ORA represents the field, the field offices, field personnel, the field laboratories, and in other words, they're our closest contact with state and local food and drug safety programs.

AFDO is supporting right now an initiative for integrating of resources for food safety. This means more and improved communication, coordination and interaction is going to be essential.

Currently many may not realize that the Office of Regulatory Affairs has sponsored and implemented and is using joint planning with state officials, whereby meetings are held, and workload within that particular jurisdiction is discussed, and plans are made for how the coverage is going to be made with respect to food safety in those industries.

We also participate in joint investigations where both federal and state or local officials go into an establishment for an investigation. This proves to be very beneficial because, though the laws are very similar and requirements of the law, if administrative and enforcement powers are different between the federal and states, then the states do have embargo authority, which we can use in a joint investigation.

ORA has developed partnerships with the states where a state has an industry fully under control. Then we develop a partnership where we share information, FDA maintains an oversight, and the state then can carry on that particular activity. In Florida, for example, we have this on our farms for pesticide residues, and it has resulted in the elimination of duplication of efforts between state and federal agencies and much better data sharing between the two.

Integration, as I mentioned, requires a strong relationship between the state programs, with our representatives at AFDO and the Office of Regulatory Affairs. In

addition to the field activities I've talked about, we also utilize laboratories, and exchange analysis, and many of our analysts have been training in laboratories up here.

The training branch is located within the Office of Regulatory Affairs. Part of the opposition to more fully integrating the food-safety system is that some states don't have officials who are well enough trained to do the work at an equivalent level to the FDA.

That's a training issue, and we're partnering with the FDA to develop those types of training initiatives that will ensure adequate inspectors and well-trained inspectors, even for those states that lack resources to be able to do that.

Obviously we are working shoulder to shoulder, and this requires endless communication, and ORA, through its federal and state relations division, is always developing new and better tools for communication to states.

Many years ago we used to only hear about issues on Friday afternoon or when the media, local media, called our office. But now

with the new communication mechanisms that have been implemented by the Office of Regulatory Affairs, FDA is keeping us abreast of emerging issues. We have moved from minimal communication at the federal level to a very close partnership of sharing, and ORA has led the way.

Again, AFDO appreciates the opportunity to comment on these very important matters. Thank you.

MR. DYKSTRA: I appreciate the words from both Betsy and Nancy. They are trying very hard to work with our state, our constituent groups, all those people that have a vested interest day in and day out for what FDA does. You don't want to get into a situation where we have to begin to take or think about taking some sort of regulatory action. That's what we're all trying to prevent.

I often tell people that the basic mission of FDA is to get good products on the market and get bad products off the market. And obviously we want to be engaged more in the former rather than, well, we want to be equally

engaged in both activities. We want to make sure that there are good products out there at all times.

So what we want to do now to continue the program is take a look at some of your questions, and myself, Joe Baca and Ballard Graham, we've divided up the questions that you've submitted. Some of those questions actually got answered on air, so we won't try to answer those questions again or offer any divergent viewpoint. They've already been answered by our headquarters folks.

So what I want to do is I'll take a crack at the first one here, and we can, we'll alternate around. And if you want to interrupt at any time and ask some questions that didn't occur to you during the course of the broadcast, feel free to do that.

The first one that I want to take a crack at comes from Sharon Harris here in the front from the American Red Cross. She asks or says that the annual meeting held in New Orleans, and I take it that was an FDA-sponsored meeting with the blood industry, with FDA and the blood manufacturers is very

informative and beneficial. Would it be possible to conduct a similar meeting on a local level? And I assume what you mean at different local levels around the country in different cities.

I think that we, FDA, is very interested in doing this sort of thing. Sometimes it's a matter of resources, trying to do these. And we try to do them in such a way that we get the broadest possible coverage. But this is something that will be answered by both ORA, as well as the center for biologics has an interest in this as well.

But I think it's a good question, and I think it's something that we probably can address and maybe address more on the local level so that we can have more of these kind of meetings.

And the second part is: What is the plan to expand FDA inspections into transfusion services?

MS. HARRIS: Hospital transfusion services.

MR. DYKSTRA: That's something we'll have to refer to the center of biologics

because they're directing most of the programs in terms of the inspection. And whether they want the field people to do more inspections in those kind of services tends to be more their call than our call. But this question will be directed to them, and they'll have to answer it. So we'll see what they answer with.

MS. HARRIS: Thank you.

MR. DYKSTRA: Joe?

MR. BACA: The question I have is: How is FDA planning to address dissemination of information regarding dietary supplements, herbal drugs, homeopathic products?

I will say that, as far as dietary supplements and herbals, our web site is a great source of information for all that kind of material. The other place that is a good source is our public affairs specialist. Every district has a public affairs specialist, and they're available by telephone. And they have a great deal of information at their fingertips that they can provide to a consumer or the industry.

The consumer magazine has run a number of articles on these kind of products,

and they're all out there and available probably through the web site. But there is a great deal of information out there. Of course, the information is coming to light daily, and so we may not be right on the cutting edge. But there's a great deal of information already there.

Some of the products that are known to cause problems are included, as well as some of the less obvious ones.

MR. DYKSTRA: Ballard?

MR. GRAHAM: I have an interesting one here. It says the drug manufacturers claim that with the high cost of getting a new drug product through FDA directly impacts the market and drug costs to the consumer. With the growing number of uninsured in America, what is FDA's plan to limit or control the cost of new drug processes? Remember often the end consumer must decide if they can afford a product or not, even though the product may best help the patient.

This was one we're certainly going to refer up, but I'll take a crack at answering some of this. I know that we have made some

improvements in the way we're processing the drug approval process, and we try to control costs that way.

Of course, the industry is kicking in some funds to help with that process as well. I think we sped up that process in trying to get those things through a lot quicker, although the consumer, I think all of us want a certain amount of information or a certain amount of review done on products when they come through for a new drug or something like that for use with the consumer.

The result is out here. Bob Coleman is a resource. He deals with us a lot on these. Do you have anything to deal with that?

MR. COLEMAN: No.

MR. GRAHAM: We'll certainly refer to headquarters for additional information on this.

UNKNOWN SPEAKER: One other thing on that is in prior years the agency has been real big on the generic drug issue, and we have listed generic drugs that have got a patent expiration on it, but it has really lowered the

prices on a lot of prescription drugs. And we put a priority on doing those inspections and getting those drugs marked.

MR. GRAHAM: That's true.

MR. DYKSTRA: Before I get to the next written question, are there any questions or comments from the audience? Okay. The next question comes from John Ostrander, and his question is: Traditionally drug definitions have included USP, NF and homeopathic pharmacopeal products. The homeopathic pharmacopeal products are not mentioned on the list of drugs pharmacies will be allowed to use for compounding. Are there plans to revisit this item and add the homeopathic pharmacopeal drugs to the list of approved drugs for compounding?

It's a very complicated issue in terms of what pharmacists and pharmacies are going to be allowed to compound in their own practices. The agency is charged with identifying specific compounds, specific drugs that pharmacists will be allowed to utilize to compound drugs based on a physician's script, prescription.

Now, what has happened though is we were proceeding along in doing that and developing the list, as John mentions here, but the, we have been sued over this whole issue of compounding. And the issue has kind of come to a screeching halt while we're waiting for this, some of these compounding issues to be litigated to see if, you know, the law, number one, is constitutional and, number two, you know, meets all the other legal challenges.

So that's likely to drag out as we all know. You know these things tend to drag on in court. Meanwhile, we don't get the answers, all the answers that we would like to this. You know, the things that Congress intended us to do will not be done as expeditiously as most people would like.

On the issue of including homeopathic products in the compounding list, that's something that the center is and was considering. We'll have to see. We'll forward this question in and see if those products are going to be included in the list when and if that list ever becomes reality. So we'll see what happens in that area.

Another one, Joe?

MR. BACA: This is a question from Betsy Woodward. FDA is looking at stronger integration of food-safety programs from the federal, state and local jurisdictions in order to leverage all available resources to maximize effectiveness. Where are we with respect to bringing all of the stakeholders, industry, consumer groups and academia, into discussion?

I think the bringing it into state and local groups is kind of getting under way. We have had two national meetings. We had one last December, and I think the previous one was in September. And that is a new concept, and I think we're working our way through it.

On the other hand, we have traditionally worked with the industry, industry groups, individual companies. For example, when an industry, a company, is going to open a new facility, we have provisions in our procedures that allow us to go in, look at blueprints, discuss with the firm, you know, how they're going to proceed and how they're going to make the facility so that they don't run afoul of the regulations with the law.

I think what's going to happen in the future, if I can look that way, is we're going to see more of that kind of interaction. I don't think we'll go back in the other direction. This is going to go back to our headquarters and be made aware that these concerns exist.

MS. WOODWARD: We've actually met with the consumer activist groups, which are really unhappy that they hadn't been included in some of the discussion groups, and we told them, the regulatory people that I knew, what FDA would have on there.

MR. BACA: One thing at a time. Bring the state and locals in first, and then span our horizons from there.

MR. DYKSTRA: Okay. Next question is from Peggy Davis, has to do with the inhalation of fragranced products which are known to trigger migraines and asthma. The EPA names the use of chemically formulated personal care products along with pesticides and household cleaners as contributors to indoor air pollution. How do you propose to raise public awareness of possible health risks from

the use of these products?

This is a, it's a difficult question. It's one that Peggy has raised with us previously. It's something that we are going to refer to our cosmetics people in particular, and it's also one that, you know, as she points out, is an EPA issue as well.

So we've got to see what, if anything, the Environmental Protection Agency is doing on this issue. So this is one, again, as promised, it will go on the web site with the response that will come primarily from our headquarters folks. So we'll see how they deal with it and see where we go from there. Do you have any others, Joe?

MR. BACA: I have one more. With this one maybe we can have more dialogue. As regulators maybe we don't realize there's a problem. This is submitted by David Mullis of London International. The question is: How and when do you see FDA's role and responsibility being clarified with that of OSHA in the area of medical devices?

I guess my thinking was I never knew we had that big of a problem. OSHA's role

is certainly to protect the health of workers, and our role is more geared toward the patient. But maybe we need to address that issue some more. Is Mr. Mullis here? Yes, sir.

MR. MULLIS: There are certain devices, particularly those that deal with latex products, that you have got FDA that has the premarket clearance authority quite clearly delineated. But I think of OSHA as a safe working environment and responsibilities in terms of enforcement of that type of thing.

And sort of like the previous question, as it gets into, you know, risk to the environment, risk to the patient, risk to the people around, there is obviously more and more concern as to who has the authority and what role is there.

I think a letter back in December came out talking about where FDA was going to allow more and more authority through OSHA for inspection kind of activities at the hospital setting. And obviously that, it's stuff that is not clearly defined, and those of us in the industry have some degree of anxiety about it.

MR. BACA: Latex is a big problem,

and with the infiltration of the use of gloves, I think it's more of a problem. Both of those will help address us on this issue.

MR. DYKSTRA: I think there currently are perhaps more than one work group looking at the specific issue of latex, and those kind of materials that can cause reactions in people, are sensitive to different materials. Whether it's gloves or just handling other types of biomaterials can cause problems for these people. That's all the questions that I have.

MS. WOODWARD: I have one question. Do you put your work groups out on the web site so interested individuals who want to participate in them can ask your industry? FDA work groups, are they listed somewhere on the web?

MR. DYKSTRA: Not to my knowledge.

MS. WOODWARD: It might be a good thing to do. It might give the Agency a sense of more openness. Really, I think that would probably be a good thing to consider at least.

MR. DYKSTRA: Because, you know, we do have work groups all over the place.

MS. WOODWARD: I know. There are some that are more interesting to the industry.

MR. DYKSTRA: It would be a good way to identify issues. Usually when a difficult issue comes up, it takes more than one person to take a look at it.

MS. WOODWARD: Absolutely.

MR. OSTRANDER: I want to put this on as a consumer issue. But recently I was very, very surprised to have a new fellow employee come to me and say they were an asthmatic. They were recently under the HMO that we had at work, and albuterol was generically substituted for Proventil. They're supposed to be generic substitution, and that if it's not in the orange book listed, you shouldn't have gotten it.

Well, I was wrong. When I discussed this with the pharmacy people in terms of substitution, if the product is out there on the market labeled as U.S.P., presumably because that's what it was, that there is no requirement for bioequivalency to the product the physician may have originally prescribed for the pharmacies to substitute

these things. At least this is what I was led to believe from the pharmacist when I spoke to him on the phone.

I think what might be needed would be some clarification to those of us who may be practitioners in the practitioner setting as to exactly what the criteria are for generic ratings in terms of the orange book listing and where that rating is not necessary for the generic product to get marketed.

Because I was just blindsided from this thing, and I was very surprised to see this.

MR. DYKSTRA: I don't have a specific answer to that, but we'll capture that as a question and pose it to the people who are more expert on it. Other questions or comments?

MR. LAWRENCE: I've got a statement. I'm Mallory Lawrence. I'm with the FDA. I'd like to see, Betsy, this is kind of directed to you. We've had an excellent working relationship with AFDO, the local organization, and AFDO overall. But I think, and when we work with them on other programs to

try to bring the seafood industry, this is seafood industry, into compliance, I'd like to see AFDO go one step further.

Because one of the shortfalls we've got, one of the problems we've got in the seafood industry is the industry is small in the southeast, and they're not regulated by most standards. I think what's needed is for AFDO to promote and AFDO to maybe carry out to facilitate specialized training in fields that there are not very many trainers located in.

For instance, the pasteurization process, salting, smoking. I think if AFDO would work with the universities and put on specialized training, I think that's the next step that needs to be taken.

We've already done the training, and we're working further on that. Now, a little bit of technical knowledge will go a long way, and I think this will, I think that's a need. And I don't think that the experts who wrote that are doing, at least at the wholesale level and into the three states that we've got, and not only can you provide training to industry, but you can train, you could provide

training on specific technical issues to the states, health and agriculture, as well as to us, our people too.

So I think that's the next step to consider where you would offer valuable assistance to industry and FDA and the states alike.

MS. WOODWARD: AFDO has a big training thrust right now, and we are seeking grant money to do just some of the things you're talking about. We're going to have to do it through some kind of a grant. Right now we're looking at trying to get a grant for smoking, curing in the sausage, smoked and cured hams. That's going on in retail that are not covered.

We are also doing some training in imports with trying to partner with Nancy's group in doing some medical-device regulation training. So we are looking at more and more training.

As much as possible, we're doing that with AFDO's resources. But like FDA we don't have a lot of resources. So we're now learning to write grants. I'd like to go on

the Hill to Congress and say, please give FDA funds similar to what U.S.D.A. has, where you can partner with associations, not just AFDO, but national, city and county health organizations, to accomplish some of these very needed things in the food-safety arena.

MR. DYKSTRA: You know, we can direct that question and comments right back at FDA, and particularly to the center, to direct some of that, some of their money their food-safety money, to people that could put on that kind of training, whether it's directed to AFDO or directly to universities and others who put on that.

MS. WOODWARD: I think we partner with a university and take it through regions to get it across the country on a cost-effective basis.

MR. DYKSTRA: Right. Other questions or comments? Well, again, I want to remind you that all of this is going to appear on the web, including a web cast for the next 30 days, of what you saw today, so you can look at it again if you thought you missed something.

And I'll also remind you that there is a formal docket for this that you can get from Joanne, and you can, if you have any questions later that occur to you, you want to get them in, you can either submit them directly or get them to Joanne, and we'll get them into the docket.

Okay. Thank you for joining us today. It's been very helpful, and I think we've all learned something. Thank you.

(Meeting adjourned at 4:15 p.m.)

C E R T I F I C A T E

GEORGIA

COBB COUNTY

I hereby certify that the above and foregoing pages 1 through 46 are a true, complete, correct and exact transcript of my shorthand notes taken in the above-referenced matter;

That same constitutes a true, complete, correct and exact record of the above-referenced matter;

That same was transcribed through computer assisted transcription;

That I am not of kin or counsel to any of the attorneys or parties, nor am I in the regular employ of any of the attorneys or parties;

This 4 day of May, 1999.

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